REMARKS/ARGUMENTS

Status of the claims

Claims 1-3, 5, and 9-12 are pending. Claim 8 is canceled. Claims 1-3, 5, and 9-12 are amended as follows. No new matter is added.

Claim 1is amended to recite "prophylactic treatment against feline infectious peritonitis virus (FIPV) infection" instead of "treating/preventing feline infectious peritonitis". In addition, the claim has been amended to specify that the vaccine comprises a polypeptide selected from the group consisting of new (a) to (d). Support can be found, *e.g.*, on page 12, lines 9-14; and page 27 lines 8-12, as well as the original claim 1(a) to (e).

Claim 2 is similarly amended, and specifies that the vaccine comprises a polynucleotide selected from the group consisting of (a) to (e). Support can be found, *e.g.*, on page 12, lines 9-14; and page 27 lines 8-12, as well as the original claim 2(a) to (e).

Claims 3 and 9 are amended to reflect the amendments to claims 1 and 2.

Claims 5 and 10-12 are amended to recite "conferring cellular immunity against a feline infectious peritonitis virus (FIPV)." Support can be found, *e.g.*, on page 5, lines 24-30; page 14, line 31; page 15, lines 4-7; page 22, lines 23-26; page 44, line 9 to page 45, line 7; and page 51, line 17 to page 52, line 8.

Formal matters

Applicants note that the Drawings as filed and Foreign priority documents are not acknowledged in boxes 10 and 12 on the Office Action Summary. Both the Drawings and Japanese Appl. No. 2002-196290 (filed July 4, 2002) were filed January 5, 2005, and appear on Private PAIR. In addition, the Japanese application appears in Private PAIR under Foreign Priority. Applicants request clarification of these matters.

Rejection under 35 USC § 112, first paragraph - Enablement

The Examiner has rejected claims 1 and 3-7 as allegedly lacking enablement under the first paragraph of 35 USC § 112. According to the Examiner, the claimed invention is

drawn to a vaccine for treating and/or preventing feline peritonitis, and the office interprets the term "prevention" as denoting absolute prevention of infection of even a single cell by a virus and absolute elimination of infection of any cell by a virus.

For the sake of clarification, Applicants note that, prior to entry of this amendment, claims 1-3, 5, and 9-12 included the term "preventing."

Solely in an effort to expedite prosecution, Applicants have amended claims 1-3 and 9 recite a "vaccine for prophylactic treatment against" FIPV infection. Amended claims 5 and 10-12 recite a "method for conferring a cellular immunity against" FIPV. The term "prophylaxis" is not used as an absolute term in the present specification (*see, e.g.*, page 27, lines 10-20). Similarly, the term "conferring cellular immunity," as used in the present specification, does not imply an absolute effect (*see, e.g.*, page 5, lines 24-30). In making these amendments, Applicants make no admission as to the appropriateness of the rejection.

In view of the amendments to the claims and foregoing comments, Applicants respectfully request withdrawal of the enablement rejection under the first paragraph of 35 USC § 112.

Rejection under 35 USC § 103

The Examiner has rejected claims 1-3, 5 and 8-12 as allegedly obvious over Wasmoen *et al.*, US Patent No. 5,770,211, in view of Motokawa *et al.* (1996) *Microbiol. & Immunol.* 40:425-433. According to the Examiner, Wasmoen teaches a FIPV vaccine comprising the N protein of FIPV and Motokawa teaches SEQ ID NOs:1 and 2 from the present application. The Examiner asserts that it would have been obvious to one of skill to use the FIPV sequence taught by Motokawa in a FIPV vaccine because Wasmoen teaches that a FIPV N protein is effective for vaccines.

Legal standard

Section 2142 of MPEP sets forth the three criteria that the Examiner must meet to establish a *prima facie* case of obviousness.

> First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The Supreme Court in *KSR* warned against overly rigid application of the so-called teaching/ suggestion/ motivation (TSM) test of obviousness and essentially expanded the field of knowledge from which a motivation to modify or combine the references could be drawn. The motivation to combine may be explicit or implicit and may be found in the knowledge of one of ordinary skill in the art, scientific principles, or legal precedent. *See* MPEP § 2144. However, the Examiner must still establish that one of skill in the art would have a reasonable expectation of success in making the claimed invention. *See* MPEP § 2143.02.

KSR also affirmed the importance of secondary considerations to a determination of obviousness, as set forth in *Graham v. John Deere Co. of Kansas City* (383 U.S. 1, (1966)). *See KSR v. Teleflex*, 127 S. Ct. 1727, 1739 (2007). As set forth in MPEP § 2145, secondary considerations include evidence of unexpected results.

The Examiner has not shown that one of skill would reasonably expect a vaccine as recited in the present claims to be effective for prophylactic treatment or conferring cellular immunity in a cat

First, we would like to note that there are two types of FIPV, "Type I" and "Type II. Most FIPV vaccines that have been investigated so far are against Type II, especially "S-protein" of the Type II FIPV. While there is a report on attempts to develop a FIPV vaccine using N-protein of Type II FIPV as an antigen, no report on an attempt for developing a vaccine against FIPV using a N-protein of Type I FIPV was provided before the present application was filed (*see, e.g.*, page 1, line 26 to page 2, line 7; page 3, line 28 to page 4, line 8; page 6, lines 2-21 of the present application).

Secondly, Wasmoen acknowledges ineffectiveness of the N-protein of Type II FIPV as a vaccine against FIPV (col. 1, lines 51-54), and then presents new approach for use of recombinant N- and E1 protein of Type II FIPV in a racoon poxvirus host. Thus, Wasmoen

discloses introduction of recombinant N protein with different antigenicity for use as a vaccine from such ineffective N-protein previously known (col. 1, lines 64-67). Wasmoen never teaches the use of N-protein of Type I FIPV as a vaccine against FIPV.

Third, Motokawa merely discloses the amino acid sequence of an N protein of a Type I FIPV (SEQ ID NO:2), and never teaches use of the N protein as an antigen for a vaccine against FIPV.

A person of skill in the art would not have a reasonable expectation of success using a Type I FIPV N protein, as described in the present application, in a vaccine for the prophylactic treatment against FIPV. The present application describes why the person of skill never attempted to develop an FIPV vaccine using a Type I FIPV N protein. As explained on page 6, beginning at line 9:

> On the other hand, there are no reports of vaccines that utilize type I N protein. This may be due to reasons such as the following: First, since type I FIPV proliferates slowly during tissue cultivation, it can be said to be a difficult experimental material to handle. Furthermore, type I FIPV is less pathogenic for cats than type II FIPV, resulting in a low rate of FIP onset. For these reasons, the design of type I FIPV infection experiments is difficult, and thus the use of type I FIPV as a material for FIP vaccine research is accompanied by difficulties.

The disclosure also explains that, even with Type II FIPV, design of an effective vaccine from the N protein is unlikely since the N protein does not exist on the surface of viral particles (see the paragraph bridging pages 5-6). Thus, a person of skill would be dissuaded from attempting to use an N protein, especially one from a Type I FIPV, for a vaccine component.

The presently claimed invention surprisingly promotes an immune response in cats infected with both Type I and Type II FIPV

Notwithstanding this knowledge in the art that teaches away from using a Type I FIPV protein, the present inventors sought to overcome these difficulties. The Examples

demonstrate that the vaccine comprising the recited amino acid sequence, derived from Type I FIPV N protein, is not only effective for prophylactic treatment against Type I FIPV, but also Type II FIPV (*e.g.*, pages 42-58, in particular, "Measurement of Cellular Immunity," and Figs. 10, 11, 15, and 16). For example, page 58, lines 37-36, explains that cats infected with either Type I or Type II had reactive sera to the Type I N protein vaccine. These results are not expected, given the differences between the Type I and Type II viral sequences (*see, e.g.*, Motokawa, Figure 3 and Table 2).

Conclusion

A person of skill would not expect to successfully confer cellular immunity and reduce FIPV infection using (i) a Type I FIPV antigen-derived vaccine or (ii) an FIPV N protein-derived vaccine. However, use of the recited Type I FIPV N protein-derived vaccine resulted in surprisingly successful treatment of both Type I and Type II infected cats. In view of the foregoing comments, Applicants respectfully request withdrawal of the rejection under 35 USC § 103.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,

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